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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,359	09/10/2004	Johan Bernard Ubbink	115808-504	.5698

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BELL, BOYD & LLOYD LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER

BADR, HAMID R

ART UNIT	PAPER NUMBER
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1709

NOTIFICATION DATE	DELIVERY MODE
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08/22/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/507,359	Applicant(s) UBBINK ET AL.	
	Examiner Hamid R. Badr	Art Unit 1709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 9, 10 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-12 and 13 is/are rejected.
- 7) ☒ Claim(s) 9, 10, 12 and 14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claim 12 is objected to because of the following informalities: A dependent claim cannot depend on itself. Appropriate correction is required.
2. Claims 9, 10 and 14 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. Claim 8 is already multiply dependent. See MPEP § 608.01(n). Accordingly, the claims 9, 10, and 14 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Okonogi et al. (US 4888171)

Regarding Claim 1

5. Okonogi et al. disclose a granular product containing dried viable microorganism cells, which has been protected against permeation of environmental moisture and atmospheric oxygen (Col. 2, lines 36-39). They also teach of the materials used in the

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formation of the core of their product (Col. 3, lines 9-23). The coating of their product is explained in terms of the composition and function. They teach of the use of the binding materials for coating the product in order to protect it against permeation of the environmental moisture and atmospheric oxygen. They further explain the use of shellac or zein for enteric coating (Col. 5, lines 17-34; Col. 8, lines 33-46). They specify their granular product to have a mean diameter of 1.5 mm (Col. 9, lines 1-2). Assuming a spherical shape, the mean granule volume is calculated to be 0.99 mm^3 .

Regarding Claim 2

6. Okonogi et al. teach of making a granular product containing dried viable bacterial cells, the product being substantially free of water (Claims 1 and 4). They also mention that the water content of the core material is preferably as low as possible, less than 5% (w/w) (Col. 3, lines 22-23). Assuming a water content of 7% (w/w) to be equivalent to a_w 0.39, the 5% water content proposed by Okonogi et al. will be below a_w 0.3.

Regarding Claim 4

7. Okonogi et al. disclose the viable count of lactic acid bacteria in their product to be 14×10^8 cells/g. The survival rate has been calculated to be 98% (Col. 9, lines 6-13). It is claimed that the cell survival rate in their product exceeds that of the conventional product during prolonged storage periods (Abstract, Table 1, Table 2, Table 3).

Regarding Claim 5

8. Okonogi et al. teach of the materials to be used for composing the core of their product. They clearly teach of materials such as sugar or sugar/starch composition

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(fillers) which can be pelletized. Use of dried viable microorganisms (functional ingredient) in the core is disclosed (Col. 3, lines 9-23). Use of binding and plasticizing materials (fats/oils, propylene glycol fatty acid ester) is further disclosed and examples of binding materials are given (Col. 3, lines 30-34). Use of lubricant is disclosed in experiment 2 (Col. 6, formulation table).

Regarding Claim 6

9. Okinogo et al. explain the use of sugar/starch compositions to be used for the core of their product. They mention that almost anything edible that can be pelletized may be used in the core of their product including palletized dried viable microorganisms (Col. 3, lines 13-23).

Regarding Claim 7

10. Okonogi et al. disclose the concept of coating their granular product in order to protect it from environmental moisture and atmospheric oxygen. (Col. 2, lines 36-39). They further explain the use of various coating materials, which provide palatable taste, flavor, color and enteric coating. (Col. 5, 17-34; Col. 8, lines 33-46).

11. Claims 1, 3, 8, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Lengerich (WO 99/48372).

Regarding Claim 1

12. Van Lengerich discloses a product that contains encapsulated live organisms. The matrix composition of his invention comprises a plasticizer and a substantial amount of a free flowing mixture (page 3, lines 8-15). The coating of the pellets is

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discussed in example 2 and 3 (page 35 and 36). He discloses the dimensions of the product where the extruded rope may have a cross sectional diameter 0.5 mm to about 3 mm. Assuming an average pellet diameter of 1.75 mm, the pellet volume is calculated to be about 1.5 mm^3 .

Regarding Claim 3

13. Van Lengerich describes the product to be non-expanded, non-puffed, and substantially non-cellular. It is also mentioned that the starch is substantially ungelatinized, and not substantially destructrized or dextrinized. Specific densities of the products are disclosed to be about 0.8 to 1.5 g/cm^3 (Page 33, lines 8-13).

Regarding Claim 8

14. Van Lengerich teaches of the use of the pellets as food or their incorporation into foods. A variety of foods having various moisture levels are mentioned (Page 34, lines 3-16). His product comprises at least one component of the food e.g. yogurt which can contain nonfat dry milk, or gelatin, or lactose (page 34, line 13).

Regarding Claim 13

15. Van Lengerich teaches of the incorporation of pellets containing live mircro-organisms into various foods where the food and the pelleted product share at least one ingredient. He mentions that the encapsulated product may be incorporated, with or without grinding, into foods for human or animal consumption. The foods, which are exemplified do share, at least, one component with the granulated product (Page 33, lines 14-23 and page 34, lines 1-2).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okonogi et al.

18. Okonogi et al. teach making particles by pelletizing various ingredients including saccharides, and acid crystals. They mention that particles of such materials and any other edible material may be prepared by pelletizing these materials. For instance, dried viable microorganisms, a pelletized product of such powder mixes may be used as the core material. They also acknowledge that dried viable bifidobacterium cells may be mixed with dried starch in order to extremely decrease the water content thereof to prepare pelletized confections (Col. 2, lines 13-16). They are silent on the water activity (a_w) of the pellets. They mention that the water content of the core materials is preferably as low as possible, less than 5% (w/w). Assuming 7% (w/w) moisture content to be equivalent to a_w 0.39, a product having 5% moisture will have a_w below 0.3. They also specify their granular product to have a mean diameter of 1.5 mm. Assuming a spherical shape for the particles, a mean volume of 0.99 mm^3 is calculated for such particles. The 20 mm^3 pellet volume proposed by applicant, is a variation of the particle volume.

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19. The above references teach how to make the product, how to coat it, and how to keep the water activity at specific levels to increase the shelf life of the product.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have adopted the process for making pellets with viable microorganisms, adjusting the water activity to levels cited above expecting a longer shelf life.

20. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okonogi et al. in further view of Klapwijk et al. (EP 0298605)

21. Klapwijk et al. disclose the process of making supported lactic acid bacterial compositions where the water activity of the supported flora products is 0.3 or less, particularly 0.2 or less. They also mention that improved storage life is provided with values 0.15 or less (Page 3, lines 47-49).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have adopted the process of palletizing the probiotic organisms and to have adjusted the moisture levels for a longer shelf life.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hamid R. Badr whose telephone number is 5172703455. The examiner can normally be reached on M-F 7:30-5:00 ET (First Friday Off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, D. Lawrence Tarazano can be reached on 5712721515. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. LAWRENCE TARAZANO
PRIMARY EXAMINER

A large, stylized handwritten signature in black ink, consisting of several loops and a long horizontal stroke, is written over the printed name and title.